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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,535	01/15/2002	Augustine M. Choi	13681-003002	7091

26161 7590 05/16/2005

FISH & RICHARDSON PC
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BOSTON, MA 02110

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,535

Applicant(s)

CHOI ET AL.

Examiner

Frank I. Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-47, 50, 53-140 is/are pending in the application.
- 4a) Of the above claim(s) 79-88 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43-47, 50, 53-59, 62, 63, 65-78, 89, 96-99, 102, 104-115 and 118-140 is/are allowed.
- 6) ☒ Claim(s) 60, 61, 64, 90-95, 100, 101, 116 and 117 is/are rejected.
- 7) ☒ Claim(s) 103 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20041013</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges Applicant's indication of withdrawn rejections and concurs with the same.

Claim Objections

Claim 103 is objected as dependent on rejected claim 64.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 64 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 95/35105.

WO 95/35105 expressly discloses a method of transdermally administering carbon monoxide to remedy carbon monoxide deficiency in human or animal organisms which consequences of deficiency phenomenon include inflammatory processes falling within the scope of Applicant's claims (Pg. 5,6). A person with carbon monoxide deficiency would be at risk of inflammation in any organ. Remedying the carbon monoxide deficiency would remedy inflammation.

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Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978). See also *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 60,61, 90-95, 100,101,116,117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maxwell et al. (Abstract) in view of Campbell (Abstract).

Maxwell et al. teach that exposure of animals bearing transplantable tumors to carbon monoxide resulted in a decrease in the rate of tumor growth.

Campbell teaches that inhalation of carbon monoxide retarded development of cancer of the skin and primary adenoma of the lungs in mice.

The difference between the claimed invention and the prior art is that the prior art does not expressly disclose the treatment of cancer in a human patient by administering inhaled carbon monoxide. However, the prior art amply suggests the same as it is known that it is effective in the treatment of cancer in animals. As such, it would have well within the skill of and one of ordinary skill in the art would have been motivated to use the same in humans with the expectation that inhaled carbon monoxide would be effective in treating cancer in humans.

Examiner has duly considered Applicant's argument but deems them unpersuasive.

Applicant argues that Maxwell and Campbell teach away from using CO as a therapeutic agent. However, this does not overcome the fact that Maxwell in combination with Campbell disclose that administration of CO resulted in treatment of cancer and reduction of tumors. The

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safety of the procedure or lack thereof is insufficient to overcome the rejection herein. See In re Jansen, 187 USPQ 743,745,746 (CCPA 1975).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 10/13/2004 and amendment prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

May 11, 2005


Alton Pryor
Primary Examiner
A. U. 1616

